# Exhibit 1


# StimGuard Clinical Trial Site Agreement

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StimGuard LLC ("Sponsor"), a Corporation, in accordance with Title 21 CFR Part 812.43, located at 901 East Las Olas Boulevard, Fort Lauderdale, FL 33301, enters into this Clinical Trial Site Agreement ("Agreement") as of the date of last Party signature below ("Effective Date"), with Cornell University for and on behalf of its Joan and Sanford I. Weill Medical College ("WCMC") located at 1300 York Avenue, New York, NY 10065, and The New York and Presbyterian Hospital ("Hospital") a hospital affiliated with WCMC (together, WCMC and Hospital are the "Site"). Sponsor, WCMC, and Hospital are each a "Party" and together the "Parties" to this Agreement.

Whereas, Sponsor engages Site to conduct a clinical study entitled "Multi-center, Prospective, Randomized, Controlled, Non-Inferiority, Clinical Trial of Chronic Afferent Nerve Stimulation (CAN-Stim) of the Tibial Nerve versus Sacral Nerve Stimulation (SNS) in the treatment of Urinary Urgency Incontinence resulting from Refractory Overactive Bladder (OAB) - PROTECT Study" (the "PROTECT Study" or "Study") according to the provisions of this Agreement and the PROTECT Study Protocol 30-00137 Rev. 7 (as amended, the "Protocol", which is incorporated herein by reference).

The Parties agree:

## 1.0 Definitions and Abbreviations

### 1.1 Authorized Third-parties

"Authorized Third-Parties" shall mean people and organizations that are subject to obligations of confidentiality at least as restrictive as those contained herein to protect Confidential Information. and who have been informed of their obligations.

### 1.2 CRF (Case Report Form)

A "CRF" shall mean a printed, optical or electronic document designed to record all of the Protocol-required information to be reported to the Sponsor on each Subject.

### 1.3 GCP (Good Clinical Practice)

"GCP" shall mean a standard for the design, conduct, performance, monitoring, auditing, recording, analysis and reporting of clinical trials, that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity and confidentiality of subjects are protected, as adopted in the U.S., by the FDA and set forth in the United States Code

of Federal Regulations ("CFR").

### 1.4 Intellectual Property

"Intellectual property" shall mean such inventions, expressions of ideas, discoveries, devices, data, mechanisms, substances, works, trade secrets, know-how, formulae and methods, including improvements, whether or not protectable by patent, copyright or other intellectual property rights.

### 1.5 Invention

"Invention" shall mean any inventions, developments, discoveries or improvements, whether or not protectable by patent, conceived and reduced to practice, in whole or in part, by or on behalf of Site pursuant to its conduct of the Study as anticipated and specified in the Protocol.

### 1.6 Investigator

The "Investigator" shall mean the Site's employee, Dr. Bilal Chughtai, who will serve as principal investigator for conduct of the Study at the Site.

### 1.7 IRB (Institutional Review Board)

"IRB" shall mean the ethics committee responsible for ensuring the protection of the rights, safety and well-being of human subjects involved in the Study.

### 1.8 Material Findings

"Material Findings" shall mean results from a Sponsor's site monitoring visit or data safety monitoring, which could affect the safety or care of Subjects, alter a Subject's willingness to participate in the Study, alter the risk-benefit ratio of the Study, influence the conduct of the Study, alter the IRB's approval, or would otherwise require changes to the informed consent form.

### 1.9 Publication

"Publication" shall mean a paper, article, manuscript, report, poster, internet posting, presentation slides, abstract, outline, video, instructional material, presentation (in the form of a written summary), or other public disclosure of Study Results, in printed, electronic, oral or other form.

### 1.10 Personnel

"Personnel" shall mean Investigator, Sub-investigators and other Site employees and contractors who assist Investigator in the conduct of the Study for the Site.

### 1.11 Recipient

The "Recipient" shall mean the Party to this Agreement that receives Confidential Information from its Owner.

### 1.12 Results

"Results" shall mean the methods, data, analysis and conclusions of the Study as set forth in the Protocol.

### 1.13 Site Indemnitees

The "Site Indemnitees" shall mean Site, Investigator, Indemnified Employees, officers, trustees, directors, appointees, IRB, privacy board, agents, contractors, subcontractors and affiliates, if any, and their assigns.

### 1.14 Source Documents

"Source Documents" shell mean original documents, data, and records (e.g., hospital records, pharmacy dispensing records, x-rays, etc.), including without limitation all medical records, but excluding CRFs.

### 1.15 Specimen

A "Specimen" shall mean a biological sample, such as blood or tissue, from a Subject, collected per the Protocol.

### 1.16 Sponsor Data

"Sponsor Data" shall mean Study lab test results, CRFs and other reports completed by Site or Investigator per the Protocol, excluding Source Documents and genetic data. Sponsor Data specifically excludes Site's results derived from analysis of data.

### 1.17 Statement of Investigator

A "Statement of Investigator" shall mean the equivalent of Form FDA 1572 for studies of medical devices under an FDA Investigational Device Exemption, as set forth in U.S. 21 CFR Parts 812.43(c) 812.100 and 812.110.

### 1.18 Sub-investigator

A "Sub-investigator" shall mean a physician or other qualified person who assists Investigator by performing Study procedures and/or making important Study decisions in accordance with the Protocol and applicable law.

### 1.19 Subject

A "Subject" shall mean each person who enrolls in the Study, including contributes a Specimen for use in the Study.

### 1.20 Test Article

The "Test Article" shall mean the Sponsor's device, chronic afferent nerve stimulation ("CAN-Stim"), under investigation in the Study and provided for the Study.

### 1.21 Interstim

"Interstim" shall mean the Medtronic device, sacral nerve stimulation also called interstim, under evaluation in the Study.

## 2.0 Duties of the Sponsor

### 2.1 Protocol and Amendments

Sponsor has provided Site with a comprehensive and accurate Protocol and supporting information necessary for Site to evaluate and conduct the Study. The Protocol will be considered effective following its approval by Sponsor, IRB, and the FDA or other applicable regulatory authority as required by law. Site will conduct the Study in accordance with the Protocol. Any modification or addendum to the Protocol must be approved by the IRB to become effective.

### 2.2 Test Article and Materials

(i) Sponsor will provide to Site on a timely basis, the required quantities of properly labeled Test Article and other materials (e.g., CRFs) needed by Site to conduct the Study per the Protocol. Sponsor will also provide to Site any needed replacement Test Article, as well as instructions for proper handling and storage. All such items are and will remain the sole property of Sponsor until administered or dispensed to Subjects during the course of the Study. Sponsor will maintain the equipment in working order and maintain property insurance on it. In accordance with applicable laws and the Protocol, the Interstim will be obtained by Site for the Study.

(ii) Sponsor warrants that:

A. It has obtained all necessary governmental and regulatory approvals to conduct the Study and provide the Test Article including without limitation, all applicable FDA approvals; and that all approvals will be in full force and effect during the Study.
B. Test Article has been manufactured and has passed quality control tests, in accordance with applicable regulations.
C. It has disclosed to Site and applicable government authorities all relevant, material information concerning the safety, use, efficacy and Test Article experience.
D. To the best of its knowledge after reasonable inquiry, use of the Test Article for Study purposes will not infringe the intellectual property rights of any third-party.
E. Any hazardous material packaging provided by Sponsor meets regulatory requirements for Site's use according to the Protocol.

WITHOUT LIMITING SPONSOR'S OBLIGATIONS UNDER SECTIONS 8 (SUBJECT INJURY) AND 9 (INDEMNIFICATION), SPONSOR DISCLAIMS ANY OTHER REPRESENTATIONS AND WARRANTIES, WRITTEN OR ORAL, EXPRESS OR IMPLIED, WITH RESPECT TO THE TEST ARTICLE, INCLUDING ANY

REPRESENTATION OR WARRANTY OF PERFORMANCE, MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE OR PURPOSE.

### 2.3 Sponsor Monitoring

Sponsor will monitor Site in accordance with regulatory requirements and may audit Site's performance of the Study and use of Sponsor's funds. Visits will be at the mutual convenience of the Parties and with reasonable advance notice and consideration for Site. Sponsor will communicate any Material Findings to Site in an exit meeting or in writing within 2 days. Site will promptly correct any deficiencies found during audits.

### 2.4 Data Safety Monitoring

Sponsor will comply with 21 CFR sections 312.32(c), 312.55(b), 812.40 and 812.150(b) in informing Site of serious adverse effects, new uses, or significant new information that could affect the safety of Subjects, their willingness to continue participation, or the risk-benefit ratio, or which could alter the IRB's approval to continue the study or require changes to the informed consent form.

## 3.0 Duties of Site and Investigator

### 3.1 Inspection

Site will, to the extent permitted by law, notify Sponsor if any government or regulatory authority begins to conduct, or gives notice of its intent to conduct, an inspection pertaining to the Study. Site and Sponsor will provide the other Party with copies of all pertinent written and electronic documents issued by the government or regulatory authority pertaining to such inspection. Site will also provide Sponsor with a copy of all written and electronic documents that otherwise pertain to the Study that are received from or provided to the government or regulatory authority, subject to confidentiality and privacy restrictions. Site will promptly correct any deficiencies found during inspections.

### 3.2 Conduct of Study

Site has the expertise, time and resources to conduct the Study per this Agreement. Site will conduct the Study in a timely manner and in accordance with this Agreement, the Protocol. Site will conduct the Study in conformance with GCP and in accordance with all applicable federal, state and local laws and regulations. The Site will accurately collect and record Study data in accordance with the Protocol and applicable law.

Site represents that neither it, nor to the best of its knowledge, any of its Personnel, are currently debarred, disqualified, or banned by FDA from conducting clinical trials or is under investigation by FDA for debarment, disqualification or any similar regulatory action. Site will, to the extent permitted by law, notify Sponsor of any actual or threatened disqualification, debarment or other ban that comes to its attention during the course of the Study.

### 3.3 Financial Disclosure

Site will require that, prior to their participation in the Study, Investigator and any Sub-investigators complete and return to Sponsor the Financial Disclosure Certification Form FDA 3455 provided by Sponsor.

### 3.4 Conflict of Interest

Each Party acknowledges that Site and Investigator (a) have no other obligation that would prevent it/him/her from the conduct of the Study, and (b) have received no offer by Sponsor or its affiliates of extra benefit for participation in the Study, including offers to family members. Site and Sponsor will promptly notify the other if it becomes aware of any conflict during the term of this Agreement that will prevent it from completing the Study under this Agreement. Site and Investigator will not knowingly enter into any financial security transaction based on Study data or Results in violation of applicable law.

### 3.5 Investigator

Investigator will personally supervise the Study and may not delegate this duty. He/she may, however, delegate other duties to qualified Personnel per Protocol and applicable regulatory requirements.

If Investigator cannot carry out his/her duties under this Agreement, or leaves Site, Site will notify Sponsor. Site may nominate a replacement investigator, whom Sponsor, at its sole discretion, may approve or reject. If Sponsor rejects the proposed replacement, a Party may terminate this Agreement upon written notice. Site may not replace Investigator or substantially reduce his/her role in the Study without Sponsor's prior written approval.

### 3.6 Sub-investigators and Other Personnel

Site will require that adequate numbers of qualified Personnel are assigned to the Study to meet its obligations under this Agreement and that all Sub-investigators and other Personnel have the necessary licenses and certifications, if applicable, and are qualified by education, training and experience to perform their Study roles.

### 3.7 Facilities

Site will conduct Study only at facilities that are listed on its Form FDA 1572. Site will require that they remain adequate during the Study in accordance with law. Sponsor may inspect Study facilities during monitoring visits pursuant to Section 2.3 and on mutually-agreeable dates during Site's normal business hours, subject to and in accordance with applicable laws.

### 3.8 IRB

Site will conduct Study with the initial and continuing approval of an IRB.

### 3.9 Study Initiation

Site will initiate Study only after the IRB has approved the Study's Protocol, informed consent form, and subject recruitment materials, as applicable, Sponsor has received a copy of these approvals, and this Agreement has been fully executed.

### 3.10 Compliance

Site will comply with applicable government, IRB and Protocol requirements regarding safety reporting, particularly with respect to serious adverse events, IDE safety reports, and Protocol violations affecting Subject eligibility or Subject safety.

### 3.11 Study Documents

Site will prepare, maintain and retain complete, current, accurate, organized and legible Source Documents, regulatory documents, and other Study documents, in accordance with applicable law and the Protocol. Site will retain in a safe and secure location all Source Documents and Sponsor Data for the longer of (a) two years after the last marketing authorization for the Test Article has been approved or Sponsor has discontinued research on the Test Article or (b) such longer period as required by regulatory requirements. Sponsor will notify Site within 30 days after this retention requirement has expired. Sponsor will reimburse Site for any subsequent storage costs plus management fee annually, upon receipt of invoice and reasonable supporting documentation. When Site destroys records, it will do so in a manner that ensures that their confidentiality is protected in accordance with applicable law.

### 3.12 Enrollment

Enrollment in Study is competitive. Site will enroll Subjects to the Study in accordance with the Protocol.

### 3.13 Adverse Events

Consistent with 21 CFR 312.64, Investigator shall, if applicable, report to Sponsor any serious adverse drug event occurring during the Study, whether or not considered drug related, and will include an assessment of where there is a reasonable possibility that the drug caused the event. Investigator shall keep a record of non-serious adverse drug events and report them to Sponsor per the Protocol. Consistent with 21 CFR 812.150, Investigator shall report to Sponsor any unanticipated adverse device effect occurring during the Study promptly, but in no event later than 10 working days after Investigator first learns of the effect.

### 3.14 Protocol Violation and Deviations

Site will notify Sponsor after becoming aware of any material Protocol violation in accordance with the Protocol and applicable law. Site will record Protocol deviations in the Study records in accordance with the Protocol and applicable law. Without prior approval, Site may deviate from the Protocol to protect Subject from an immediate hazard. Any such deviation will not constitute a failure to comply with the Protocol. To the extent possible, Site will address any violations and deviations in accordance with applicable law and the Protocol.

### 3.15 Informed Consent

Investigator will ensure that informed consent, is obtained from Subjects, or that an IRB approved waiver of informed consent is obtained, prior to screening for, or participation in, the Study, in accordance with applicable law. Both Parties will ensure that the informed consent form, when applicable, is consistent with Section 6.4 (Data & Specimen Ownership) and Section 8 (Subject Injury) and applicable law. Both Parties will approve the form. When Subject safety or medical care could be directly affected by Study results, Site will communicate that information to Subjects in accordance with applicable law.

### 3.16 Test Article

Site will verify to Sponsor receipt of the Test Article. Site will store the Test Article and empty containers in a safe and securely locked area per Protocol requirements. Site will maintain complete and accurate records on the receipt and disposition of Test Article and empty containers. Site will use Test Article only for Study purposes according to the Protocol. Site will not dispense expired Test Article to Subjects.

Site will use any equipment provided by Sponsor only for the Study or such other purposes as Sponsor may approve in writing. Site will return equipment in working order with normal wear and tear excepted, at Sponsor's cost, to Sponsor promptly, using reasonable efforts to return within 45 days, after completion of the Study by Site or termination of this Agreement.

### 3.17 Communication of Results to Subjects

Sponsor will inform Site of Study results when the information is available to Sponsor. For a period of 2 years after the Study, Sponsor will inform Site of any Study results which could directly affect Subject safety or medical care.

### 3.18 Return of Study Materials

Promptly following the conclusion or premature termination of the Study or termination of this Agreement, Sponsor will instruct Site to return or destroy any unused Study materials, including Test Article, CRFs and equipment furnished by Sponsor. Promptly thereafter, Site will comply with Sponsor's reasonable written instructions. Sponsor will provide shipping materials and pay Site's out-of-pocket shipping costs. During the Study, Site may return unused materials to Sponsor with prior Sponsor approval.

## 4.0 Confidential Information

### 4.1 Confidential Information

(i) "Confidential Information" shall mean information, in any form, provided by or on behalf of a Party ("Owner") to Recipient under this Agreement for the Study that is treated by the Owner as confidential or proprietary and would be identified as confidential or proprietary by a reasonable person experienced in the field of clinical research.

Sponsor Confidential Information, where Sponsor shall be deemed the Owner and Site deemed the Recipient, shall include the Protocol, Sponsor Data, Sponsor Inventions (as defined in Section 6.5), and Investigator's Brochure for the Test Article.

Site Confidential Information, where Site shall be deemed the Owner and Sponsor deemed the Recipient, shall include Specimens.

Confidential Information, as used in this Agreement, shall include Sponsor Confidential Information and Site Confidential Information.

(ii) This Section 4 does not apply to Confidential Information that is not confidential because it:

A. is, or subsequently becomes, in the public domain, through no breach of this Agreement by Recipient;
B. was lawfully in Recipient's possession prior to disclosure by Owner, as shown by written records or other competent evidence;
C. was lawfully disclosed to Recipient by a third-party under no obligation to keep such information confidential; or
D. has been lawfully developed independently by Recipient, as evidenced by contemporaneous written documentation or other competent evidence.

**4.2 Disclosures**

(i) Confidential Information may be disclosed by Recipient if it:

A. is required to be disclosed in a government inspection, or by a government order, order by a court of competent jurisdiction, or other federal or state laws;
B. is required by a third-party payor about a Subject, to the extent necessary to determine coverage;
C. is required to verbally answer Subject's reasonable questions during the informed consent process;
D. is required by Recipient or third-party physician for medical treatment or counseling of Subjects or other persons exposed to Test Article;
E. is required to be disclosed to protect the public's health;
F. is reasonably required for publication of Study data and results pursuant to Section 7 of this Agreement; or
G. is required by Recipient to defend itself in Subject injury litigation, subject to prior written notification to Owner.

(ii) Disclosures under this Section 4.2 are limited according to the Recipient's reasonable judgment to the extent necessary in order to comply with the terms of this Agreement.

If a disclosure of Confidential Information is required by a government order, court of law, other federal or state laws, or a Subject as described above, Recipient will disclose only such

Confidential Information as is required and only to the party that requires the disclosure. It will otherwise maintain the confidentiality of Confidential Information to the extent possible.

(iii) For clarity, this Section does not limit Site's disclosure rights under Sections 7 (Publications) or Section 13.2 (Publicity and Use of Names).

### 4.3 Confidentiality Obligations

(i) During the term of this Agreement and for five (5) years thereafter, Recipients will use Confidential Information only for the purposes set forth in this Agreement. Recipients will protect Confidential Information with at least the same care as they use to protect their own confidential information of a comparable nature, and in no event will they use less than reasonable care. Recipient will disclose Confidential Information only to their employees or personnel involved in conducting the Study or performance of this Agreement, who are bound by a similar obligations of confidentiality, on a need-to-know basis, and who have been informed of their obligations.

(ii) Promptly following termination or expiration of this Agreement and written request by the Owner, Recipient will destroy (with certification to Owner) or return to Owner at Owner's expense, Owner's Confidential Information that it is not required to be retained by law, regulation or other legal requirement. However, Recipient may retain one copy of Confidential Information for its records in a secure location.

(iii) A breach of this Section 4 may cause irreparable damage that may not be addressed adequately by money damages. In addition to any other remedies that may be available, the Owner is therefore entitled to seek injunctive relief to prevent or restrain a breach of this Section.

## 5.0 Protected Health Information and Use of Data.

(i) Each Party and Investigator will comply with applicable laws and regulations governing the privacy and security of Subject information, including the Health Insurance Portability and Accountability Act of 1996 and the regulations promulgated thereunder ("HIPAA") and applicable amendments thereto. Site will obtain written authorization from Subjects or IRB waivers of authorization to use and disclose Subjects' protected health information as defined in HIPAA ("PHI") to the extent necessary to conduct the Study and provide Study data to Sponsor in accordance with the Protocol and applicable law. These authorizations or waivers of authorization will allow disclosures of the minimally necessary PHI to permit the Sponsor to comply with this Agreement, applicable laws, regulations and legal requirements.

(ii) Sponsor is not a HIPAA Covered Entity, but it will not:

A. use Subject information except for purposes of the Study and as authorized by Subject;
B. disclose Subject identifying information or disclose Subject private information to any third-party unless required to do so by law, regulation, government order, or pursuant to a written request by the Subject;
C. leave Subject private information unsecured;

D. remove Subject information from Site; or

E. attempt to contact any Subjects.

(iii) Each Party (a) shall implement appropriate safeguards to prevent the use or disclosure of PHI as required under the federal regulation and standard (b) will report to the other any use or disclosure of PHI not provided for by this Agreement as soon as a Party becomes aware of such use or disclosure and (c) shall make available its internal practices, books, and records relating to the use and disclosure of PHI to the U.S. Secretary of Health Services to the extent required for determining compliance with the federal privacy regulations and the security standards. Notwithstanding the foregoing, neither Party waives its attorney-client, accountant-client, or other legal privilege by virtue of these provisions.

## 6.0 Intellectual Property

### 6.1 Separate Property

Intellectual Property that either Party owned prior to execution of this Agreement, or develops independently of the Study and other Party's Confidential Information, is that Party's separate property. It is not affected by this Agreement. Neither Party has any claims to or rights in such Intellectual Property of the other Party, except as expressly stated in this Agreement.

### 6.2 Site Authority

Site represents that it has the authority to grant all of the rights granted in this Section, and that its Investigator and Personnel are obligated to assign any Inventions to Site.

### 6.3 Disclosure

Promptly after becoming aware of any Invention, Site will disclose the Invention to Sponsor with a reasonable written description.

### 6.4 Data & Specimen Ownership

Sponsor owns all Sponsor Data. Site owns all Source Documents. Site owns all Specimens and Specimen genetic data. Site grants Sponsor access to Specimens and such data only for purposes of the Study in accordance with applicable law and the Subject informed consent form. Sponsor and Site may freely use their own data subject to Subject consent and IRB approval. In addition, Site may freely use Sponsor Data for academic, internal research, patient care and internal noncommercial use, subject to Section 4 and 7 of this Agreement. Sponsor has no right to Site's pre-existing biological samples, genomic database, or other proprietary database.

### 6.5 Ownership of Inventions

Sponsor will own Inventions conceived and reduced to practice, in whole or in part, through use of the Test Article, or concerning methods of using Test Article, or otherwise related to the Test Article or Sponsor Confidential Information ("Sponsor Invention"). Site will retain the right to use such Sponsor Inventions internally for patient care, research, education and publication, provided such use does not breach Section 4 of this Agreement. The sole or joint ownership of

all other Inventions will be determined in accordance with U.S. patent law, regardless of whether the Invention is patentable. Sponsor and Site may independently exploit joint Inventions that are not Sponsor Inventions without compensation, liability or other obligation to the other Party, subject, however, to Section 6.6 (License).

Without Sponsor's prior approval, Site will not knowingly use in the Study any of its own or third-party Intellectual Property that would interfere with Sponsor's rights to Inventions.

### 6.6 License

Site hereby grants Sponsor an exclusive one-time option, without fee, exercisable within thirty (30) calendar days following written notice of an Invention ("Option Notice"), to negotiate an exclusive license, to all rights, title and interest that Site may have or obtain in that Invention. Upon Sponsor's exercise of its option with regard to any particular Invention, Site and Sponsor will negotiate in good faith for up to six (6) months from the date of Option Notice, or within such additional time the Parties may mutually agree in writing ("Negotiation Period") in an attempt to reach a license agreement satisfactory to both Parties. If an agreement is not reached by the end of that Negotiation Period, or if Sponsor does not exercise its option, then Sponsor's rights to that Invention will expire, and Site will have no other obligation to Sponsor with respect to such Invention. Any exclusive license for an Invention shall be subject to Site's right to use such Invention for internal, non-commercial academic, research and patient care use. Site hereby grants Sponsor, for the term of the Negotiation Period, a non-exclusive, worldwide (to the extent permitted by law), royalty-free license on Site's rights to the Invention for Sponsor's internal research purposes.

### 6.7 Filings

At Sponsor's request and expense, Site will execute, or cause to be executed by its Investigator and any Personnel, all documents and perform all acts, necessary to evidence Sponsor's ownership of Sponsor Inventions, obtain patents in any country (to the extent permitted by law), and otherwise protect Sponsor's interests in Sponsor Inventions.

Sponsor may incorporate Source Document data in any regulatory filing concerning the Test Article to the extent required by applicable law and permitted by the Subject informed consent form. The inclusion of Source Document data in any regulatory filing gives Site no ownership, license or access rights in, or to, such regulatory filing(s) or Test Article.

For any joint Inventions, Sponsor may elect to file joint patent or other intellectual property applications at its own expense. It will notify Site within fifteen (15) days of such election, and will provide Site with copies of any applications it files and of any written communications to or from the applicable patent or other intellectual property office regarding any such joint Invention.

### 6.8 License to Site

Upon Site's request, after Sponsor has filed patent applications or otherwise protected its Sponsor Inventions according to this Section 6 (Intellectual Property), and subject to Section 4

(Confidential Information), Sponsor will grant Site a perpetual, non-exclusive, royalty-free license to use Sponsor Inventions to perform the Study, for its internal educational, non-commercial research, and patient care purposes, and to comply with any applicable laws and regulations.

## 7.0 Publication

### 7.1 General

Site may use any Results and Sponsor Data arising out of its conduct of the Study for Publication, provided that Site does not disclose Sponsor Confidential Information (except Results and Sponsor Data), and allows Sponsor time to protect its proprietary rights, as provided below in this Section 7. Sponsor will make available to Site for Publication purposes Sponsor Data created at Site.

At least thirty (30) days prior to submission for publication or presentation, Site will submit a copy of any proposed Publication to Sponsor. Sponsor may review the Publication to (a) determine whether the Publication discloses Sponsor Confidential Information (other than Results and Sponsor Data), and (b) determine whether the Publication discloses any potentially-patentable Inventions.

Sponsor will submit to Site in writing, within thirty (30) days of receipt of a Publication: (i) any request to delete Sponsor Confidential Information and Site will delete any Sponsor Confidential Information other than Results and Sponsor Data, however, such deletions are not required if they cause the Publication to be incomplete, inaccurate, misleading or preclude publication by Site of the Study's Results; and (ii) any request to delay Publication, and Site will withhold Publication from submission for sixty (60) days in addition to the initial 30-day review period or until Sponsor files patent applications to establish and preserve Sponsor's proprietary rights, whichever occurs first. Alternatively, Site may delete information pertaining to the potential Invention from the Publication.

If Sponsor does not exercise its rights under this Section within the time periods stated in this Section, Site may submit the Publication for publication or presentation.

### 7.2 Multicenter Articles

Study is part of a multicenter trial, and Sponsor intends that the first Publication is to be a joint Publication covering all Study sites, and that any subsequent Publications by participating sites will reference that primary multicenter Publication. Therefore, Site agrees not to publish hereunder until the first to occur of (i) publication of the results of the multicenter Study data, (ii) notification by Sponsor that such a multicenter Publication is no longer planned, or (iii) the date twelve (12) months after completion or termination of Study at all participating sites, subject to the other requirements of this Section 7.

### 7.3 Registry

Sponsor will comply with FDA requirements to register studies and ICMJE's current Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publications: Obligation to Register Clinical Trials, including Sponsor will register the Study at www.clinicaltrials.gov.

## 8.0 Subject Injury

If any Party to this Agreement becomes aware of a Subject injury or illness that may have been caused by the Study, that Party will inform promptly, using reasonable efforts to inform within five (5) days of such awareness, the other Party of the injury or illness. The Parties will reasonably cooperate to determine the relationship, if any, of the Study to the injury or illness.

Sponsor will pay all reasonable and actual fees for standard-of-care diagnosis, care and treatment of the injury or illness caused by the Study, including the Test Article administered in accordance with the Protocol or a Study procedure performed in accordance with the Protocol; provided however, Sponsor will not pay:

A. to the extent that the injury or illness was caused by Site's breach of this Agreement, including any deviation from the Protocol, or failure to comply with written instructions consistent with the Protocol provided by Sponsor to Site, or applicable laws and regulations, except to protect the safety and welfare of the Subject;
B. to the extent that the injury or illness was caused by the negligence or willful misconduct of Site or Investigator; and
C. to the extent that the injury or illness is attributable to any underlying illness, unless such injury or illness was exacerbated by the Test Article.

Sponsor payments pursuant to this Section 8 will be made as follows (a) Sponsor will pay for such costs that are denied or not otherwise paid for by a private third-party payor; (b) Sponsor will pay for such costs for any uninsured patients; and (c) claims for such costs for Medicare and Medicaid subjects will be submitted to Sponsor for payment, and any balance not paid for by Sponsor will be submitted to Medicare or Medicaid, subject to applicable Medicare and Medicaid billing rules and regulations.

## 9.0 Indemnification

10.1 Indemnification. Sponsor will defend, indemnify and hold harmless Site Indemnitees from any and all third-party liabilities, claims, actions, lawsuits, and expenses, including reasonable attorneys' and experts' fees and costs ("Liability(ies)"), to the extent that they arise in whole or in part from:

A. Site Indemnitees' participation in the Study, including administration or use of any Test Article, proper performance of any Study test or procedure, use of any equipment or supplies provided by Sponsor, or complying with the Protocol or any written instructions provided by Sponsor; or
B. any:

i. patent infringement, copyright violation, or trade secret misappropriation caused by use of the Test Article by Site;
ii. handling, use or subsequent transfer of Specimens and genetic data shipped by Site per Sponsor's written instructions consistent with the Protocol;
iii. Sponsor's use, non-use, interpretation or disclosure of Study data, PHI, Source Documents, Sponsor Data, or Results;
iv. design, manufacture, sale, promotion or use in commerce by Sponsor or its licensee of any product, service or process relating to the Study;
v. (i) violation of any law or regulation, (ii) material breach of this Agreement, or (iii) negligence, recklessness, or intentional misconduct, by Sponsor or its employees, officers, agents, subcontractors or other authorized third-party that takes on those roles;
vi. Sponsor act or omission in designing the Study, writing the Protocol, or providing written instructions to Site;
vii. injury (including bodily injury and death) caused by the administration of the Test Article or the performance of any procedure required under the Protocol; or
viii. manufacturing defect of the Test Article.

10.2 Exceptions. This indemnification obligation does not apply to the extent that the Liability is determined by a court of competent jurisdiction to result from:

A. any Site Indemnitee breach of this Agreement, including not conducting Study in accordance with
   i. the Protocol;
   ii. written instructions provided by Sponsor that are consistent with the Protocol; or
   iii. applicable laws and regulations, provided that Site Indemnitee's actions were not necessary to protect the safety or welfare of the Subject; or
B. the negligence, recklessness, or willful misconduct of any Site Indemnitee.

10.3 Procedure. Site may elect to defend itself and waive its indemnification rights for any specific claim in writing to Sponsor. This waiver does not apply if a Court of competent jurisdiction orders Site to retain its own counsel. Site will notify (with all material information) Sponsor promptly upon becoming aware of any claim or reasonable likelihood of a potential claim of indemnification rights under this Section. Site will cooperate fully, at Sponsor's reasonable expense, in the defense or settlement of any claim, action or lawsuit; provided however, each Site Indemnitee may participate in any such claim, action, or lawsuit at it/his/her own expense. Such cooperation includes reasonably attending hearings and trials, reasonably assisting in securing and giving evidence, and reasonably attempting to obtain the attendance of necessary and proper witnesses; but not disclosing information privileged under law. Site will permit Sponsor or its insurance carrier to defend or settle such claim or lawsuit with the cooperation and reasonable participation of Site. Site may retain its own counsel, at its own expense, to monitor the defense. Site will not compromise or settle any claim or action that is the subject of Sponsor's indemnification obligations without Sponsor's prior consent, which shall not be unreasonably withheld or delayed. Site's failure to cooperate or give prompt notice as

provided above will not relieve Sponsor of its indemnification obligations except to the extent that such failure and delay in notification materially prejudices the defense of the claim, action, suit or complaint. If Site does not elect to defend itself, Sponsor has the sole right to select defense counsel, subject to consent by Site as permitted under Sponsor's insurance policy, and to control the defense or settlement of any such claim, action or lawsuit; providedhowever, Sponsor may not effect any compromise or settlement of a third-party claim that includes an admission of liability or a financial obligation on the part of the Site Indemnitees without Site's or such Site Indemnitee's prior written consent.

## 10.0 Insurance & Liability

### 10.1 Site Insurance

Site warrants and represents that it has a general liability and medical malpractice insurance program to cover its, Investigator's and Personnel responsibilities hereunder and any insurance Site may provide shall be excess and noncontributory, and shall not be construed as an indemnity of Sponsor or any third party by Site.

### 10.2 Sponsor Insurance

Sponsor shall provide sufficient evidence of employer's liability insurance with minimum limits of $1,000,000 per occurrence and $1,000,000 in the aggregate and Sponsor will provide sufficient evidence that Sponsor can meet the statutory requirements of workers' compensation insurance. If any automobiles are used in connection with the performance of this Agreement, Sponsor shall provide sufficient evidence of commercial automobile liability insurance with a combined single limit of not less than $1,000,000 per occurrence for bodily injury and property damage and such insurance shall cover the Sponsor for all owned, non-owned and hired vehicles used in connection with the performance of this Agreement. Sponsor shall ensure that its insurer/s add as additional insureds to the insurance required herein: "Cornell University, for and on behalf of its Joan & Sanford I. Weill Medical College" and "The New York and Presbyterian Hospital" with the certificate of insurance holders identified as Cornell University, c/o Joan and Sanford I. Weill Medical College, Attn: Joint Clinical Trials Office with an address at 1300 York Avenue, New York, NY 10065 and The New York and Presbyterian Hospital with an address at 525 East 68th Street, New York, NY 10065. Sponsor agrees to provide a certificate of insurance evidencing the required insurance coverage to Institution's Joint Clinical Trials Office (1300 York Avenue, Box 305, New York, NY 10065). The certificate holder shall be Cornell University, c/o Joan and Sanford I. Weill Medical College, Attn: Joint Clinical Trials Office, 1300 York Avenue, Box 305, New York, NY 10065.

Sponsor shall carry general liability insurance (including coverage for bodily injury, property damage, and contractual liability), with limits of at least $3 million per occurrence and $5 million in the aggregate, and the insurance should be written on an occurrence basis. Sponsor shall carry products liability insurance, including clinical trial coverage, with limits of at least $3 million per occurrence and $10 million in the aggregate. This insurance shall be primary. Sponsor represents its insurance (or comparable self-insurance) covers the Study and is not materially encumbered by existing claims. Sponsor will maintain such coverage for the duration

of this Agreement and if the policy is claims-made, for three (3) years thereafter. Sponsor will provide certificates of insurance or evidence of self-insurance to Site upon request. Sponsor shall also provide sufficient evidence of network security & privacy liability (cyber liability) insurance with minimum limits of $5,000,000 per occurrence and $5,000,000 in the aggregate which shall be written on an occurrence basis. Sponsor will notify Site within twenty (20) days of any notice of cancellation or non-renewal of, or material change in, or claim against, its insurance coverage. Site reserves the right to terminate this Agreement in the event that Sponsor cancels, does not renew, reduces or materially changes its insurance coverage. Insurance carriers will have an AM Best rating of A-VII or better. The limits of insurance under this Section will not limit Sponsor's liability obligations, including indemnification and emergency medical care obligations, under this Agreement.

## 11.0 Effective Date, Term & Termination

### 11.1 Effective Date

This Agreement becomes effective when signed below by all Parties and the Investigator, as of the Effective Date.

### 11.2 Term

This Agreement will expire the earlier of (i) when the Study closes, including Site has submitted all CRFs to Sponsor, has resolved all data clarification queries, has submitted the closeout report to the Sponsor, and has met all other close-out Protocol obligations; (ii) five (5) years from the Effective Date, or (iii) the date earlier terminated in accordance with this Agreement.

### 11.3 Termination

The Parties may terminate this Agreement upon written notice under the following circumstances:

A. **Breach.** Upon material breach by a Party, the other Party may terminate this Agreement provided that the breaching Party fails to cure the breach within thirty (30) days after receiving notice of such breach.
B. **Subject Safety.** Either Party may terminate immediately based on Subject safety or welfare concerns, or if the IRB, FDA, or other regulatory authority withdraws approval for the Study.
C. **Insolvency.** Either Party may terminate immediately upon notice by the other Party that it has filed for protection under any bankruptcy laws, has been declared insolvent, ceases or threatens to cease to carry on its business, or an administrator or receiver has been appointed over all or part of its assets.
D. **Investigator Successor.** Either Party may terminate if Investigator is unable for any reason to continue in that role and the Parties are unable to mutually agree upon a successor.
E. **Government Exclusion.** Site may terminate immediately if Sponsor is excluded from any FDA, OHRP or Medicare/Medicaid, or other state or federal government program.
F. **Without Cause.** Either Party may terminate without cause, upon ninety (90) days' prior notice.

Upon expiration or any termination of this Agreement, Site will immediately stop enrolling Subjects and, subject to protecting Subject safety and welfare, cease performing any Study procedures, and will complete normal Study completion tasks required by the Protocol and applicable law.

### 11.4 Compensation

Sponsor will compensate Site for services provided up through effective date of termination of this Agreement and for any services provided after termination that are necessary to safeguard Subject safety or to comply with applicable laws, rules, regulations or Sponsor's requirements, all in accordance with the budget and schedule in Exhibit A. Site will return any unused refundable advances promptly after invoice by Sponsor. Sponsor will pay Site for all reasonable non-cancelable obligations properly incurred for the Study by Site prior to termination.

### 11.5 Survival

Sections 3.11, 3.18, 3.19, 4 (only for the period of time set forth in Section 4.3), 5, 6, 7, 8, 9, 11, 12, and 13 will survive will remain in full force and effect following termination or expiration of this Agreement. The Parties will reasonably cooperate with each other during and following termination or expiration of this Agreement to comply with all applicable laws, rules, and regulations.

### 11.6 Continuing Treatment

If this Agreement is terminated at any time, Sponsor will, free of charge, if requested by Site and permitted by law and regulations, use its reasonable efforts to supply Site with sufficient Test Article to treat Subjects as necessary to protect the Subject.

## 12.0 Notice

### 12.1 Provision and Time of Notice

Any notice will be in writing and deemed given (a) upon delivery in person, (b) upon documented delivery date by a nationally-recognized overnight delivery service, (c) five days after postmark of U.S. Postal Service registered or certified mailing with postage prepaid and return receipt requested, (d) upon confirmed receipt by fax or email, when recipient confirms receipt in writing.

Notices shall be sent to the address set forth below, or such other address subsequently designated by notice to the other Party.

### 12.2 Notification Parties and Addresses

#### *12.2.1 IF TO SPONSOR:*

StimGuard
Attn: Niek Vanquathem
901 East Las Olas Boulevard
Fort Lauderdale, FL 33301

Phone (for couriers use only): (800) 965-5134
E-mail: niek@freedomneuro.com
Billing: Accounting@stimguard.com

*12.2.2 IF TO SITE:*

Weill Medical College of Cornell University
Attn: Joint Clinical Trials Office
1300 York Avenue, Box 305
New York, NY 10065
Phone (for courier use only): 646-962-8215
E-mail: jctocontracts@med.cornell.edu

## 13.0 General

### 13.1 Governing Law

The laws of the State of New York shall govern this Agreement, without regard to conflict-of-laws provisions.

### 13.2 Publicity & Use of Names

The use by any Party of the name, trademark, trade name, logo, or any adaptation thereof, of any other Party, or the name of any other Party employee, in any press release, advertisement, promotional material, or promotional activity requires the prior written approval of the other Party, subject, however, to the following:

A. Sponsor may, without prior consent, identify Site as the entity that conducted the Study, and identify Investigator as conducting the Study at the site as necessary to sponsor the Study. This paragraph does not apply to information of Subinvestigators or other Study Personnel.
B. Site and Investigator may, without prior consent, disclose their participation in the Study (including the name of the Sponsor, name of the Study, Protocol number, funding amount, and any information available in a public registry) in (1) C.V.s, (2) their website, (3) a listing of the Protocol in publicly available listings of ongoing clinical trials or other subject recruitment services or mechanisms, (4) publications and presentations, (5) grant applications to non-commercial funding sources, and (6) conflict-of-interest reports. This paragraph applies to Subinvestigators and other Study Personnel.
C. This Section shall not restrict any Party's ability to use the other Party's name in regulatory filings, prosecuting or defending litigation, complying with applicable governmental regulations and legal requirements, internal reports generated in the normal course of business, and acknowledgement of sponsorship.

### 13.3 Entire Agreement; Modifications

This Agreement, together with any attached Exhibits, sets forth the entire understanding among the Parties about the Study. Any prior agreements, promises or representations, whether oral or written, such as agreements of confidentiality, with respect to matters covered by this Agreement

have no force or effect. Any modification or waiver to this Agreement must be in writing and signed by all Parties to this Agreement and by the Investigator.

### 13.4 Counterparts

This Agreement may be executed in one or more counterpart copies, each of which constitutes an original and all of which together constitute the Agreement. Execution will be complete when each Party holds a copy of this Agreement signed by each other Party and delivered by electronic or other means to such Party.

### 13.5 Authority

The Parties represent that they have the right to enter into this Agreement, that existing obligations do not materially interfere with their duties and responsibilities under this Agreement, and that the terms of this Agreement are valid and binding. Each Party represents that its signatory to this Agreement has authority to legally bind such Party to this Agreement. The signatories are not Parties to this Agreement.

### 13.6 Assignment

Any assignment of this Agreement, and the associated rights and obligations, requires the prior written consent of the other Party. This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective heirs, legal representatives, successors and permitted assigns.

### 13.7 Relationship of the Parties

Each Party is an independent contractor, and not a partner, agent, employee, representative or joint-venturer of the other Party. Except as set forth in this Agreement, no Party, or its employees, agents or subcontractors, has any right or authority to bind or act on behalf of the other Party. This Agreement creates no legal rights for any third-party. Except for the rights expressly granted herein, nothing in this Agreement shall be construed as conferring upon any party by implication, estoppel or otherwise any additional rights, including, but not limited to, any additional rights in or to confidential information, intellectual property, or inventions of other parties.

### 13.8 Severability

If a court of competent jurisdiction finds any provision of this Agreement legally invalid or unenforceable, such finding will not affect the validity or enforceability of any other provision of this Agreement and the Parties agree to negotiate in good faith to revise the provision to make it valid and enforceable, provided such revision must (a) adhere as strictly as possible to the Parties' original purposes and (b) be given such interpretation as to achieve the intent of this Agreement.

### 13.9 Remedies and Waivers

In case of breach or default of this Agreement, the Parties may pursue all contractual and other remedies, both legal and equitable. Any waiver of a provision of this Agreement will be in writing. Failure to enforce any provision will not constitute a general waiver of that provision.

### 13.10 Conflict between Agreement and Protocol

If any provision of this Agreement conflicts with a provision of the Protocol, the Protocol takes precedence on matters of medicine, and science, and this Agreement takes precedence in any other matters.

### 13.11 Force Majeure

No Party will be liable for failure or delay in performing its obligations under this Agreement if the failure or delay is caused by circumstances beyond the reasonable control of such Party, and are not specified elsewhere in this Agreement. A Party claiming force majeure will notify the other Party in writing and will use its reasonable efforts to resume performance of its obligations under this Agreement. If any force majeure continues for three (3) months, a Party may terminate this Agreement upon written notice.

### 13.12 Site Policies

If in connection with the Study or performance of this Agreement Sponsor and/or any of its agents, employees, officers or representatives come into contact with individually identifiable health information relating to patients of Site who are not Study Subjects, Sponsor agrees to, and agrees to ensure its agents, employees, officers or representatives agree to, maintain the confidentiality of such information and not to use it for any purpose. All Subject/patient medical records shall remain the property of Site, and Sponsor shall protect the identity of patient/subject as required by HIPAA, the informed consent forms and all applicable laws and regulations, and Sponsor shall otherwise comply with all applicable laws and policies of Site regarding the confidentiality of such records. Sponsor's personnel on site at any premises of Site shall comply with all applicable policies and procedures of Site, including but not limited to security, safety, infection control and patient privacy.

### 13.13 Export Controls

This Agreement is made subject to the laws and regulations concerning the export and re-export of products, services or technical information that the U.S. government may impose from time to time, and to the exceptions thereunder, such as the exception for "fundamental research" in Part 734 of Title 15 of the U.S. Code of Federal Regulations ("Export Laws"). To this end, the Sponsor shall cooperate with Site as reasonably necessary to permit Site to comply with Export Laws. The Sponsor hereby represents and covenants either: (a) that all of the Sponsor's activities contemplated by this Agreement fall within an exception to Export Laws (such as the "fundamental research" exception), and the Sponsor has executed or will execute such activities in accordance with all regulations concerning the applicable exception; or (b) that the Sponsor (i) is neither a national of nor controlled by a national of any country to which the United States prohibits the export or re-export of goods, services, or technology; (ii) is not a person specifically designated as ineligible to export from the United States or deal in U.S.-origin goods, services, or technologies; (iii) will not export or re-export, directly or indirectly, any goods, services, or technology, to any country or person (including juridical persons) to which the United States prohibits the export of goods, technology, or services; and (iv) in the event that a U.S.

government license or authorization is required for an export or re-export of goods, services, or technology (including technical information acquired from Site under this Agreement and/or any products created by using such technical information or any part thereof), the Sponsor shall obtain any necessary U.S. government license or other authorization prior to undertaking the export or re-export. Sponsor shall provide prior written notice to Site before providing to Site any items subject to export controls, and Site reserves the right not to accept such items.

**13.14 Headings**

The captions and headings are inserted only for convenience and in no way define or limit the scope of this Agreement or the intent of any provision hereunder.

**13.15 Device**

The Sponsor will invoice the Site for the cost of the Test Article in accordance with applicable law, including 21 CFR § 812.7(b). The cost will be $11,850, which is equal to price necessary for the Sponsor to recover the costs of manufacturing, researching, developing, and handling the investigational device.

Sponsor will provide an invoice along with the Test Article at time of implant. The Site will comply with applicable law to submit the invoice to insurers for reimbursement promptly after implant. Site will as required by law provide a copy of the Explanation of Benefits (EOB) for each Subject to the Sponsor. Sponsor agrees to accept the insurance payment specified on the EOB from the Site if insurance does not pay $11,850. If no payment is received from insurance, Sponsor agrees to pay the Site the implant charge on the approved budget.

Sponsor agrees to accept whatever payment is received from insurance as full payment for the Test Article.

IN WITNESS WHEREOF, the Parties hereto have executed this Agreement in duplicate by proper persons duly authorized.

**FOR SPONSOR**

**Signature** DocuSigned by: Niek Vanquathem 30A69FF7B2134B8... **Title** Vice President of Clinical Affairs

**Name** Niek Vanquathem **Date** 12/6/2018

**FOR SITE**

**Cornell University for and on behalf of its Joan and Sanford I. Weill Medical College**

**Signature** **Title** **Senior Director, Financial Management**

**Name** **Edward Walsh** **Date** 12/5/18

**The New York and Presbyterian Hospital**

**Signature** **Title** **SVP & COO**

**Name** **Katherine L. Heilpern, MD** **Date**

**Read and Acknowledged:**

**Signature** **Title** **Investigator**

**Name** **Bilal Chughtai, MD** **Date**

IN WITNESS WHEREOF, the Parties hereto have executed this Agreement in duplicate by proper persons duly authorized.

**FOR SPONSOR**

DocuSigned by:
Niek Vanquathem
50A69FF7B2134B8...

**Signature** _____ **Title** Vice President of Clinical Affairs

**Name** Niek Vanquathem **Date** 12/6/2018

**FOR SITE**

**Cornell University for and on behalf of its Joan and Sanford I. Weill Medical College**

**Signature** _____ **Title** Senior Director, Financial Management

**Name** Edward Walsh **Date** _____

**The New York and Presbyterian Hospital**

**Signature** _____ **Title** SVP & COO

**Name** Katherine L. Heilpern, MD **Date** 12/5/18

**Read and Acknowledged:**

**Signature** _____ **Title** Investigator

**Name** Bilal Chughtai, MD **Date** _____

IN WITNESS WHEREOF, the Parties hereto have executed this Agreement in duplicate by proper persons duly authorized.

**FOR SPONSOR**

**Signature** DocuSigned by: Niek Vanquathem 50A69FF7B2134B8... **Title** Vice President of Clinical Affairs

**Name** Niek Vanquathem **Date** 12/6/2018

**FOR SITE**

**Cornell University for and on behalf of its Joan and Sanford I. Weill Medical College**

**Signature** _____ **Title** Senior Director, Financial Management

**Name** Edward Walsh **Date** _____

**The New York and Presbyterian Hospital**

**Signature** _____ **Title** SVP & COO

**Name** Katherine L. Heilpern, MD **Date** _____

**Read and Acknowledged:**

**Signature** _____ **Title** Investigator

**Name** Bilal Chughtai, MD **Date** 12/5/18

## Exhibit A – Compensation Form

**Sponsor will pay the site according to the approved budget.**

## 1.0 Financial Terms

### 1.1 Budget

Sponsor will pay Site in accordance with the fee schedule in Exhibit A (Budget). This includes costs related to device purchase and procedural costs of the control device (Medtronic Interstim®) Changes to Exhibit A (Budget) may be documented by an amendment to this Agreement.

### 1.2 Payee

All payments to Site will be made by check:

Payee: Weill Medical College of Cornell University
Address: 1300 York Avenue, Box 305, New York, NY 10065
Phone: 646-962-8215
Attn: Joint Clinical Trials Office
Tax ID: 13-1623978
Email: jctofinance@med.cornell.edu

### 1.3 Payment Terms and Invoicing

Sponsor will pay site based on a single invoice on a quarterly basis for subject visit payments. All administrative costs and subject related invoiceables will be submitted by site by invoice. Payment shall be due within 30 days after receipt of invoice.

Sponsor shall reimburse Site not more often than monthly for allowable costs. All invoices shall be submitted using site's standard invoice, but at a minimum shall include current and cumulative costs, and certification as to truth and accuracy of invoice. Invoices and questions concerning invoice receipt or payment should be directed to the appropriate party's contact as shown in section 12.2.

Sponsor or its designee will perform a reconciliation of the Institutions account and submit to Institution for review and approval to jctofinance@med.cornell.edu before issuing a final payment to the Institution accounting for all previous Study payments and any remaining payments.

**Invoices:**
Invoices shall be sent to: StimGuard LLC

Sponsor Name: StimGuard
Attention to: Accounting
Sponsor Address: 1310 Park Central Boulevard South, Pompano Beach, FL 33064, USA
Sponsor Email Address: accounting@stimguard.com (CC: accounting@stimwave.com)

Any questions related to payments shall be directed to:
Payment Contact Name: Accounting
Payment Contact Email Address: accounting@stimguard.com (CC: accounting@stimwave.com)
Payment Contact Phone Number:(800)20965-5134.

| | Visit | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **CAN-Stim ARM** | Screening and Consent | | Baseline | | CAN-Stim Implant | | 2 Week Visit | | 1 Month Visit | | 3 Month Visit | | 6 Month Visit | | 9 Month Visit | | 12 Month Visit | | Total per Patient | Unscheduled Visit | |
| Informed Consent | x | $250.00 | | | | | | | | | | | | | | | | | $250.00 | | |
| Inclusion / Exclusion Form | x | $100.00 | x | $100.00 | | | | | | | | | | | | | | | $200.00 | | |
| Provide 2, 3 Day Voiding Diary | x | $50.00 | | | | | | | | | | | | | | | | | $50.00 | | |
| Demographics & Medical History | | | x | SOC | | | | | | | | | | | | | | | SOC | | |
| Physical Examination | | | x | SOC | | | | | | | | | | | | | | | SOC | | |
| Medications | | | x | $50.00 | x | $50.00 | x | $50.00 | x | $50.00 | x | $50.00 | x | $50.00 | x | $50.00 | x | $50.00 | $400.00 | x | $50.00 |
| Weight and Vitals | | | x | SOC | | | | | | | | | | | | | | | SOC | | |
| Bladder Scan PVR | | | x | SOC | | | | | | | | | | | | | | | SOC | | |
| 2, 3 Day Voiding Diary Summary Form | | | x | $50.00 | | | x | $50.00 | | | x | $50.00 | | | | | x | $50.00 | $200.00 | | |
| 1, 3 Day Voiding Diary Summary Form | | | | | | | | | x | $50.00 | | | x | $50.00 | x | $50.00 | | | $150.00 | | |
| Pre-Op Lab Tests | | | x | SOC | | | | | | | | | | | | | | | SOC | | |
| Urinalysis | x | SOC | x | SOC | | | x | SOC | x | SOC | x | SOC | x | SOC | x | SOC | x | SOC | SOC | x | SOC |
| VAS, MESA Questionnaire | x | $60.00 | | | | | | | | | | | | | | | | | $60.00 | | |
| i-QOL, OAB-q, PPIUS Questionnaires | | | x | $90.00 | | | x | $90.00 | x | $90.00 | x | $90.00 | x | $90.00 | x | $90.00 | x | $90.00 | $630.00 | | |
| Adverse Events | | | | | x | $50.00 | x | $50.00 | x | $50.00 | x | $50.00 | x | $50.00 | x | $50.00 | x | $50.00 | $350.00 | x | $50.00 |
| X-Ray of Device | | | | | x | $150.00 | | | | | x | $150.00 | | | | | | | $300.00 | x | $100.00 |
| Intraoperative Measurements | | | | | x | $150.00 | | | | | | | | | | | | | $150.00 | | |
| Implant Procedure | | | | | x | $2,200.00 | | | | | | | | | | | | | $2,200.00 | | |
| Global Response Assessment Form (GRA) | | | | | | | x | $30.00 | x | $30.00 | x | $30.00 | x | $30.00 | x | $30.00 | x | $30.00 | $180.00 | | |
| Patient Stipend | x | $150.00 | x | $150.00 | x | $150.00 | x | $150.00 | x | $150.00 | x | $150.00 | x | $150.00 | x | $150.00 | x | $150.00 | $1,350.00 | | |
| ClinCard fees | X | $5.00 | X | $1.25 | X | $1.25 | X | $1.25 | X | $1.25 | X | $1.25 | X | $1.25 | X | $1.25 | X | $1.25 | $15.00 | | |
| Investigator fees | X | $500.00 | X | $450.00 | X | $400.00 | X | $300.00 | X | $300.00 | X | $300.00 | X | $300.00 | X | $300.00 | X | $300.00 | $3,150.00 | x | $250.00 |
| Study Coordinator | X | $600.00 | X | $400.00 | X | $500.00 | X | $300.00 | X | $300.00 | X | $300.00 | X | $300.00 | X | $300.00 | X | $300.00 | $3,300.00 | x | $300.00 |
| **Sub-Total Costs** | | $1,715.00 | | $1,291.25 | | $3,651.25 | | $1,021.25 | | $1,021.25 | | $1,171.25 | | $1,021.25 | | $1,021.25 | | $1,021.25 | **$12,935.00** | | $750.00 |
| **35% Overhead** | | $600.25 | | $451.94 | | $1,277.94 | | $357.44 | | $357.44 | | $409.94 | | $357.44 | | $357.44 | | $357.44 | **$4,527.25** | | $262.50 |
| **Total Cost with 35% Overhead** | | $2,315.25 | | $1,743.19 | | $4,929.19 | | $1,378.69 | | $1,378.69 | | $1,581.19 | | $1,378.69 | | $1,378.69 | | $1,378.69 | **$17,462.25** | $0.00 | $1,012.50 |

| | Visit | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **SNS ARM** | Screening and Consent | | Baseline | | SNS Trial Implant | | 2 Week Visit | | SNS Permanent Implant | | 1 Month Visit | | 3 Month Visit | | 6 Month Visit | | 9 Month Visit | | 12 Month Visit | | Total per Patient | Unscheduled Visit | |
| Informed Consent | x | $250.00 | | | | | | | | | | | | | | | | | | | $250.00 | | |
| Inclusion / Exclusion Form | x | $100.00 | x | $100.00 | | | | | | | | | | | | | | | | | $200.00 | | |
| Provide 2, 3 Day Voiding Diary | x | $50.00 | | | | | | | | | | | | | | | | | | | $50.00 | | |
| Demographics & Medical History | | | x | SOC | | | | | | | | | | | | | | | | | SOC | | |
| Physical Examination | | | x | SOC | | | | | | | | | | | | | | | | | SOC | | |
| Medications | | | x | $50.00 | x | $50.00 | x | $50.00 | x | $50.00 | x | $50.00 | x | $50.00 | x | $50.00 | x | $50.00 | x | $50.00 | $450.00 | x | $50.00 |
| Weight and Vitals | | | x | SOC | | | | | | | | | | | | | | | | | SOC | | |
| Bladder Scan PVR | | | x | SOC | | | | | | | | | | | | | | | | | SOC | | |
| 2, 3 Day Voiding Diary Summary Form | | | x | $50.00 | | | x | $50.00 | | | | | x | $50.00 | | | | | x | $50.00 | $200.00 | | |
| 1, 3 Day Voiding Diary Summary Form | | | | | | | | | | | x | $50.00 | | | x | $50.00 | x | $50.00 | | | $150.00 | X | $50.00 |
| Pre-Op Lab Tests | | | x | $50.00 | | | | | | | | | | | | | | | | | $50.00 | | |
| Urinalysis | x | SOC | x | SOC | | | x | SOC | | | x | SOC | X | SOC | x | SOC | x | SOC | x | SOC | SOC | x | SOC |
| VAS, MESA Questionnaires | x | $60.00 | | | | | | | | | | | | | | | | | | | $60.00 | | |
| i-QOL, OAB-q, PPIUS Questionnaires | | | x | $90.00 | | | x | $90.00 | | | x | $90.00 | | | x | $90.00 | x | $90.00 | x | $90.00 | $540.00 | | |
| Implant Procedure | | | | | x | SOC | | | x | SOC | | | | | | | | | | | | | |
| Adverse Events | | | | | x | $50.00 | x | $50.00 | x | $50.00 | x | $50.00 | x | $50.00 | x | $50.00 | x | $50.00 | x | $50.00 | $400.00 | x | $50.00 |
| X-Ray of Device | | | | | x | $150.00 | | | | | | | x | $150.00 | | | | | | | $300.00 | x | $100.00 |
| Intraoperative Measurements | | | | | x | $150.00 | | | x | $150.00 | | | | | | | | | | | $300.00 | | |
| Global Response Assessment Form (GRA) | | | | | | | x | $30.00 | | | x | $30.00 | x | $30.00 | x | $30.00 | x | $30.00 | x | $30.00 | $180.00 | | |
| Patient Stipend | x | $150.00 | x | $150.00 | x | $150.00 | x | $150.00 | | | x | $150.00 | x | $150.00 | x | $150.00 | x | $150.00 | x | $150.00 | $1,350.00 | | |
| ClinCard fees | X | $5.00 | X | $1.25 | X | $1.25 | X | $1.25 | X | $1.25 | X | $1.25 | X | $1.25 | X | $1.25 | X | $1.25 | x | $1.25 | $16.25 | | |
| Investigator fees | X | $500.00 | X | $400.00 | X | $400.00 | X | $250.00 | X | $250.00 | X | $250.00 | X | $250.00 | X | $250.00 | X | $250.00 | x | $250.00 | $3,050.00 | x | $250.00 |
| Study Coordinator | X | $600.00 | X | $300.00 | X | $300.00 | X | $300.00 | X | $300.00 | X | $300.00 | X | $300.00 | X | $300.00 | X | $300.00 | x | $300.00 | $3,300.00 | x | $300.00 |
| **Sub-Total Costs** | | $1,715.00 | | $1,191.25 | | $1,251.25 | | $971.25 | | $801.25 | | $971.25 | | $1,031.25 | | $971.25 | | $971.25 | | $971.25 | **$10,846.25** | | $800.00 |
| **35 % Overhead** | | $600.25 | | $416.94 | | $437.94 | | $339.94 | | $280.44 | | $339.94 | | $360.94 | | $339.94 | | $339.94 | | $339.94 | **$3,796.19** | | $280.00 |
| **Total Cost with 35% Overhead** | | $2,315.25 | | $1,608.19 | | $1,689.19 | | $1,311.19 | | $1,081.69 | | $1,311.19 | | $1,392.19 | | $1,311.19 | | $1,311.19 | | $1,311.19 | **$14,642.44** | | $1,080.00 |

| **Additional Fees, as needed** | **WCM** |
|---|---|
| Start up Fees | $9,000 |
| Screen Failures | $2,315 |
| Close Out Fee | $3,500 |
| Archiving Fee | $3,500 |
| Protocol Amendment Fee | included in IRB amendment |
| End of Study Visit | included in budget |
| Monitoring Visit | $1500/one time fee |
| Joint Clinical Trials Office (JCTO) | $3,000 |
| IRB Initial | $2,000 |
| IRB Renewal | $2000/per year |
| IRB Amendment | $1500/per amendment |
| linical Study Evaluation Committee (CSEC) | $1,500 |
| Adminsitrative Amendment Fee | $1,000 |
| Invoicing Startup Fee | $2,500 |
| Invoice Fee | $1350/per subject visit invoice |

stim guard

Clinical Trial Site Amendment

**Amendment #1 to Clinical Trial Site Agreement**

This Amendment #1 to the Clinical Trial Site Agreement ("Amendment") is made effective as of the date of the last party to sign below ("Amendment Effective Date") by and between StimGuard LLC ("Sponsor"), a Corporation in accordance with Title 21 CFR Part 812.43, located at 901 East Las Olas Boulevard, Fort Lauderdale, FL 33301 and Cornell University for and on behalf of its Joan and Sanford I. Weill Medical College ("WCMC") located at 1300 York Avenue, New York, NY 10065, and The New York and Presbyterian Hospital ("Hospital") a hospital affiliated with WCMC (together, WCMC and Hospital are the "Site". Sponsor, WCMC, and Hospital are each a "Party" and together the "Parties" in this Amendment.

**WHEREAS,** Sponsor and Site entered into a Clinical Trial Site Agreement ("Agreement") effective December 6, 2018 regarding the clinical study entitled "Multi-center, Prospective, Randomized, Controlled, Non-Inferiority, Clinical Trial of Chronic Afferent Nerve Stimulation (CAN-Stim) of the Tibial Nerve versus Sacral Nerve Stimulation (SNS) in the treatment of Urinary Urgency Incontinence resulting from Refractory Overactive Bladder (OAB)-PROTECT Study" (the "PROTECT Study" or "Study").

**WHEREAS,** the Parties wish to amend the Agreement as set forth herein.

**NOW, THEREFORE,** in consideration of the premises and of the mutual covenants, conditions, and agreements contained herein, the parties agree as follows:

1. Section 12.2.1 "Notification Parties and Addresses" is hereby amended to state:

   ***IF TO SPONSOR:***
   StimGuard, LLC
   Address: 1310 Park Central Boulevard South,
   Pompano Beach, FL 33064, USA
   Phone: (800) 965-5134
   Email: miriam@stimguard.com
   Billing: Accounting@stimguard.com

2. Exhibit A "Compensation Form" of the Agreement is hereby amended to reflect the patient stipend amended from $150 (one hundred fifty dollars) increased to $250 (two hundred fifty dollars).

3. Section 1.2 "Payee" is hereby amended to state:

All payments to site will be made by ACH/ wire transfer payment. Sponsor will pay any transaction fees incurred for ACH/ wire transfer payment.

**Payee:**

Payee: Weill Medical College of Cornell University
Address: 1300 York Avenue, Box 305, New York, NY 10065

Clinical Trial Site Amendment

Phone: 646-962-8215
Attn: Joint Clinical Trials Office
Tax ID: 13-1623978
Email: jctofinance@med.cornell.edu

Bank Name: : JP Morgan Chase Bank
Bank Address: 360 East 72nd Street, New York, NY 10021
Account Number: [redacted]
Routing Number: [redacted]

**Payer:** StimGuard, LLC
Address: 1310 Park Central Boulevard South,
Pompano Beach, FL 33064, USA
Phone: (800) 965-5134
Attn: Accounting
Email: accounting@stimguard.com
(CC: accounting@stimwave.com, miriam@stimguard.com, novell@stimwave.com)

4. Except as amended hereby, all of the terms of the Agreement shall remain and continue in full force and effect and are hereby confirmed in all respects.

## Exhibit A: Compensation Form

| | Visit | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **CAN-Stim ARM** | Screening and Consent | | Baseline | | CAN-Stim Implant | | 2 Week Visit | | 1 Month Visit | | 3 Month Visit | | 6 Month Visit | | 9 Month Visit | | 12 Month Visit | | Total per Patient | Unscheduled Visit | |
| Informed Consent | x | $250 | | | | | | | | | | | | | | | | | $250 | | |
| Inclusion / Exclusion Form | x | $100 | x | $100 | | | | | | | | | | | | | | | $200 | | |
| Provide 2, 3 Day Voiding Diary | x | $50 | | | | | | | | | | | | | | | | | $50 | | |
| Demographics & Medical History | | | x | SOC | | | | | | | | | | | | | | | SOC | | |
| Physical Examination | | | x | SOC | | | | | | | | | | | | | | | SOC | | |
| Medications | | | x | $50 | x | $50 | x | $50 | x | $50 | x | $50 | x | $50 | x | $50 | x | $50 | $400 | x | $50 |
| Weight and Vitals | | | x | SOC | | | | | | | | | | | | | | | SOC | | |
| Bladder Scan PVR | | | x | SOC | | | | | | | | | | | | | | | SOC | | |
| 2, 3 Day Voiding Diary Summary Form | | | x | $50 | | | x | $50 | | | x | $50 | | | | | x | $50 | $200 | | |
| 1, 3 Day Voiding Diary Summary Form | | | | | | | | | x | $50 | | | x | $50 | x | $50 | | | $150 | | |
| Pre-Op Lab Tests | | | x | SOC | | | | | | | | | | | | | | | SOC | | |
| Urinalysis | x | SOC | x | SOC | | | x | SOC | x | SOC | x | SOC | x | SOC | x | SOC | x | SOC | SOC | x | SOC |
| VAS, MESA Questionnaire | x | $60 | | | | | | | | | | | | | | | | | $60 | | |
| I-QOL, OAB-q, PPIUS Questionnaires | | | x | $90 | | | x | $90 | x | $90 | x | $90 | x | $90 | x | 90 | x | $90 | $630 | | |
| Adverse Events | | | | | x | $50 | x | $50 | x | $50 | x | $50 | x | $50 | x | $50 | x | $50 | $350 | x | $50 |
| X-Ray of Device | | | | | x | $150 | | | | | x | $150 | | | | | | | $200 | x | $100 |
| Intraoperative Measurements | | | | | x | $150 | | | | | | | | | | | | | $150 | | |
| Implant Procedure | | | | | x | $2,200 | | | | | | | | | | | | | $2,200 | | |
| Global Response Assessment Form (GRA) | | | | | | | x | $30 | x | $30 | x | $30 | x | $30 | x | $30 | x | $30 | $180 | | |
| Patient Stipend | x | $250 | x | $250 | x | $250 | x | $250 | x | $250 | x | $250 | x | $250 | x | $250 | x | $250 | $2,250 | | |
| ClinCard fees | X | $5 | X | $1.25 | X | $1.25 | X | $1.25 | X | $1.25 | X | $1.25 | X | $1.25 | X | $1.25 | X | $1.25 | $15.00 | | |
| Investigator fees | X | $500 | X | $450 | X | $400 | X | $300 | X | $300 | X | $300 | X | $300 | X | $300 | X | $300 | $3,150 | x | $250 |
| Study Coordinator | X | $600 | X | $400 | X | $500 | X | $300 | X | $300 | X | $300 | X | $300 | X | $300 | X | $300 | $3,300 | x | $300 |
| **Sub-Total Costs** | | $1,815 | | $1,391 | | $3,751 | | $1,121 | | $1,121 | | $1,271 | | $1,121 | | $1,121 | | $1,121 | **$13,735** | | $750 |
| **35% Overhead** | | $635 | | $487 | | $1,313 | | $392 | | $392 | | $445 | | $392 | | $392 | | $392 | **$4,807** | | $263 |
| **Total Cost with 35% Overhead** | | $2,450 | | $1,878 | | $5,064 | | $1,514 | | $1,514 | | $1,716 | | $1,514 | | $1,514 | | $1,514 | **$18,542** | | $1,013 |

| | Visit | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **SNS ARM** | Screening and Consent | | Baseline | | SNS Trial Implant | | 2 Week Visit | | SNS Permanent | | 1 Month Visit | | 3 Month Visit | | 6 Month Visit | | 9 Month Visit | | 12 Month Visit | | Total per Patient | Unscheduled Visit |
| Informed Consent | x | $250 | | | | | | | | | | | | | | | | | | | $250 | |
| Inclusion / Exclusion Form | x | $100 | x | $100 | | | | | | | | | | | | | | | | | $200 | |
| Provide 2, 3 Day Voiding Diary | x | $50 | | | | | | | | | | | | | | | | | | | $50 | |

# Clinical Trial Site Amendment

| | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Demographics & Medical History | | | x | SOC | | | | | | | | | | | | | | | | SOC | | |
| Physical Examination | | | x | SOC | | | | | | | | | | | | | | | | SOC | | |
| Medications | | | x | $50 | x | $50 | x | $50 | x | $50 | x | $50 | x | $50 | x | $50 | x | $50 | x | $50 | $450 | x | $50 |
| Weight and Vitals | | | x | SOC | | | | | | | | | | | | | | | | SOC | | |
| Bladder Scan PVR | | | x | SOC | | | | | | | | | | | | | | | | SOC | | |
| 2, 3 Day Voiding Diary Summary Form | | | x | $50 | | | x | $50 | | | | | x | $50 | | | | | x | $50 | $200 | | |
| 1, 3 Day Voiding Diary Summary Form | | | | | | | | | | | x | $50 | | | x | $50 | x | $50 | | | $150 | X | $50 |
| Pre-Op Lab Tests | | | x | $50 | | | | | | | | | | | | | | | | | $50 | | |
| Urinalysis | x | SOC | x | SOC | | | x | SOC | | | x | SOC | X | SOC | x | SOC | x | SOC | x | SOC | SOC | x | SOC |
| VAS, MESA Questionnaires | x | $60 | | | | | | | | | | | | | | | | | | | $60 | | |
| i-QOL, OAB-q, PPIUS Questionnaires | | | x | $90 | | | x | $90 | | | x | $90 | | | x | $90 | x | $90 | x | $90 | $540 | | |
| Implant Procedure | | | | | x | SOC | | | x | SOC | | | | | | | | | | | | | |
| Adverse Events | | | | | x | $50 | x | $50 | x | $50 | x | $50 | x | $50 | x | $50 | x | $50 | x | $50 | $400 | x | $50 |
| X-Ray of Device | | | | | x | $150 | | | | | | | x | $150 | | | | | | | $300 | x | $100 |
| Intraoperative Measurements | | | | | x | $150 | | | x | $150 | | | | | | | | | | | $300 | | |
| Global Response Assessment Form (GRA) | | | | | | | x | $30 | | | x | $30 | x | $30 | x | $30 | x | $30 | x | $30 | $180 | | |
| Patient Stipend | x | $250 | x | $250 | x | $250 | x | $250 | | | x | $250 | x | $250 | x | $250 | x | $250 | x | $250 | $2,250 | | |
| ClinCard fees | X | $5 | X | $1.25 | X | $1.25 | X | $1.25 | X | $1.25 | X | $1.25 | X | $1.25 | X | $1.25 | X | $1.25 | x | $1.25 | $16.25 | | |
| Investigator fees | X | $500 | X | $400 | X | $400 | X | $250 | X | $250 | X | $250 | X | $250 | X | $250 | X | $250 | x | $250 | $3,050 | x | $250 |
| Study Coordinator | X | $600 | X | $300 | X | $300 | X | $300 | X | $300 | X | $300 | X | $300 | X | $300 | X | $300 | x | $300 | $3,300 | x | $300 |
| **Sub-Total Costs** | | $1,815 | | $1,291 | | $1,351 | | $1,071 | | $801 | | $1,071 | | $1,131 | | $1,071 | | $1,071 | | $1,071 | **$11,746** | | $800 |
| **35 % Overhead** | | $635 | | $452 | | $473 | | $375 | | $280 | | $375 | | $396 | | $375 | | $375 | | $375 | **$4,111** | | $280 |
| **Total Cost with 35% Overhead** | | $2,450 | | $1,743 | | $1,824 | | $1,446 | | $1,082 | | $1,446 | | $1,527 | | $1,446 | | $1,446 | | $1,446 | **$15,857** | | $1,080 |

| **Additional Fees, as needed** | **WCM** |
|---|---|
| Start up Fees | $9,000 |
| Screen Failures | $2,315 |
| Close Out Fee | $3,500 |
| Archiving Fee | $3,500 |
| Protocol Amendment Fee | included in IRB amendment |
| End of Study Visit | included in budget |
| Monitoring Visit | $1500/one time fee |
| Joint Clinical Trials Office (JCTO) | $3,000 |
| IRB Initial | $2,000 |
| IRB Renewal | $2000/per year |
| IRB Amendment | $1500/per amendment |
| Clinical Study Evaluation Committee (CSEC) | $1,500 |
| Adminsitrative Amendment Fee | $1,000 |
| Invoicing Startup Fee | $2,500 |
| Invoice Fee | $1350/ per subject visit invoice |

* SNS and CAN-Stim procedures should be reimbursed by patients insurance if CMS approved.
  If insurance does not cover the fee as stated per budget, StimGuard will pay the surplus fee.
* Proof of insurance denial will be required for sponsor payment of CAN-Stim and SNS payments that have been denied by the patient's insurance
* SNS procedures and device as per insurance.

DocuSigned by:

Sponsor Signature: Michael C Baja
Date: 11/21/2019

Site Signature
Date

D7ACCD23110545E...

Clinical Trial Site Amendment

IN WITNESS WHEREOF, the Parties hereto have executed this Amendment in duplicate by proper persons duly authorized:

**FOR SPONSOR**

DocuSigned by:

**Signature** Michael C Baja

**Name** Michael Baja

**Title** VP Clinical Studies US

**Date** 10/21/2019

**FOR SITE**

**Cornell University for and on behalf of its Joan and Sanford I. Weill Medical College**

**Signature**

**Name** Edward Walsh

**Title** Senior Director, Financial Management

**Date** 11/8/19

**The New York and Presbyterian Hospital**

**Signature**

**Name** Katherine L. Heilpern, MD

**Title** SVP & COO

**Date**

**Read and Understood:**

**By:**

**Name:** Bilal Chughtai, M.D.

**Title:** Principal Investigator

**Date:**

stim guard

Clinical Trial Site Amendment

IN WITNESS WHEREOF, the Parties hereto have executed this Amendment in duplicate by proper persons duly authorized:

**FOR SPONSOR**

DocuSigned by:

**Signature** Michael C Baja

B7A88D2941B545E...

**Name** Michael Baja

**Title** VP Clinical Studies US

**Date** 10/21/2019

**FOR SITE**

**Cornell University for and on behalf of its Joan and Sanford I. Weill Medical College**

**Signature** _____

**Name** Edward Walsh

**Title** Senior Director, Financial Management

**Date** _____

**The New York and Presbyterian Hospital**

**Signature** _____

**Name** Katherine L. Heilpern, MD

**Title** SVP & COO

**Date** 11/5/19

**Read and Understood:**

**By:** _____

**Name:** Bilal Chughtai, M.D.

**Title:** Principal Investigator

**Date:** _____

Clinical Trial Site Amendment

IN WITNESS WHEREOF, the Parties hereto have executed this Amendment in duplicate by proper persons duly authorized:

**FOR SPONSOR**

DocuSigned by:

**Signature** Michael C Baja

**Name** Michael Baja

**Title** VP Clinical Studies US

**Date** 10/21/2019

**FOR SITE**

**Cornell University for and on behalf of its Joan and Sanford I. Weill Medical College**

**Signature** _____

**Name** Edward Walsh

**Title** Senior Director, Financial Management

**Date** _____

**The New York and Presbyterian Hospital**

**Signature** _____

**Name** Katherine L. Heilpern, MD

**Title** SVP & COO

**Date** _____

**Read and Understood:**

**By:** Bilal Chughtai

**Name:** Bilal Chughtai, M.D.

**Title:** Principal Investigator

**Date:** 11/26/19



**Amendment No. 2 to Clinical Trial Site Agreement**

This Amendment No. 2 to Clinical Trial Site Agreement ("Amendment No. 2") is made effective as of the date of the last party to sign below ("Amendment No. 2 Effective Date"), acts as a revision to the original Clinical Trial Site Agreement ("Agreement") by and between StimGuard, LLC. ("Sponsor"), a Corporation in accordance with Title 21 CFR Part 812.43, located at 1900 Glades Road Suite 500 Boca Raton, FL 334311900 Glades Road Suite 500 Boca Raton, FL 33431and Cornell University for and on behalf of its Joan and Sanford I. Weill Medical College ("WCMC") located at 1300 York Avenue, New York, NY 10065, and The New York and Presbyterian Hospital ("Hospital") a hospital affiliated with WCMC (together, WCMC and Hospital are the "Site"). Sponsor, WCMC, and Hospital are each a "Party" and together are the "Parties" in this Amendment No. 2.

WHEREAS, the Parties wish to amend certain sections of the Agreement;

THEREFORE, the Parties agree to the following changes within the Agreement:

The Sponsor company name has changed from Micron Medical Corporation to Uro Medical Corporation, a Delaware corporation, whose address
1900 Glades Road Suite 500 Boca Raton, FL 33431
All references to Sponsor in the Agreement shall now refer to Uro Medical Corporation.

This document acts as a revision to Exhibit A "Compensation Form" of the original agreement. The additional fees are amended to exclude Screen Failures. Therefore, screen failures are no longer an invoiceable fee.

***Section 2.2 Test Article and Materials is hereby amended to state:***
Sponsor will provide to Site on a timely basis, the required quantities of properly labeled Test Article and other materials (e.g., CRFs) needed by Site to conduct the Study per the Protocol. Sponsor will also provide to Site any needed replacement Test Article, as well as instructions for proper handling and storage. All such items are and will remain the sole property of Sponsor until administered or dispensed to Subjects during the course of the Study. Sponsor will maintain the equipment in working order and maintain property insurance on it. **In accordance with applicable laws and the Protocol, the control device, Medtronic Interstim®, will be obtained by Site for the study. The Sponsor will provide the Site the Test Article in the required quantities at no cost in accordance with 21 CFR § 812.7(b). The Sponsor will pay for costs related to device purchase and procedural costs of the control device (Medtronic Interstim®) in accordance with this agreement. Sponsor will pay 100% complete cost of control device (Medtronic Interstim®) equipment and procedure.**

Site agrees that, should it receive a Test Article at no charge pursuant to this section of the Agreement, it will not seek or collect reimbursement for the Test Article from any party, including any third-party payer.



The Parties agree that Sponsor's efforts in this regard are not intended to induce the Site, Investigator, or any other individual to use, or arrange the use of, the Test Article (or any other Sponsor product), except for purposes of conducting the Study.

Sponsor warrants that:

A. It has obtained all necessary governmental and regulatory approvals to conduct the Study and provide the Test Article including without limitation, all applicable FDA and IRB approvals; and that all approvals will be in full force and effect during the Study.
B. Test Article has been manufactured and has passed quality control tests, in accordance with applicable regulations.
C. It has disclosed to Site and applicable government authorities all relevant, material information concerning the safety, use, efficacy and Test Article experience.
D. To the best of its knowledge after reasonable inquiry, use of the Test Article for Study purposes will not infringe the intellectual property rights of any third-party.
E. Any hazardous material packaging provided by Sponsor meets regulatory requirements for Site's use according to the Protocol.

Without limiting Sponsor's obligations under Sections 8 (Subject Injury) and 9 (Indemnification), Sponsor disclaims any other representations and warranties, written or oral, express or implied, with respect to the Test Article, including any representation or warranty of performance, merchantability or fitness for a particular use or purpose.

***Section 12.2.1 "Notification Parties and Addresses" is hereby amended to state:***

IF TO SPONSOR:
Uro Medical Corporation
Address: 1900 Glades Road
Suite 500
Boca Raton, FL 33431, USA
Phone: (888) 691-0585
Email: info@uromedical.com, Shanice@uromedical.com ,
Billing: accounting@uromedical.com

***Section 13.2.1 IF TO SPONSOR is amended to state:***

For Agreement Matters: Shanice Saunders, Shanice@uromedical.com

For Payment Matters: Accounting@uromedical.com .com, cc: Shanice@uromedical.com

For Legal Matters: Shanice Saunders, Shanice@uromedica.com

For Study-related Matters: Shanice Saunders, Shanice@uromedical.com

Uro Medical Clinical Trial Site Agreement Amendment

IN WITNESS WHEREOF, the parties hereto have executed this Amendment No. 2 to the Agreement by proper persons duly authorized:

**FOR Uro Medical Corporation**

| | |
|---|---|
| **Signature** | DocuSigned by: Laura Tyler Perryman |
| **Name** | **Laura Perryman** |
| **Title** | **Chief Operating Officer** |
| **Date** | 8/23/2021 |

**FOR Uro Medical Corporation**

| | |
|---|---|
| **Signature** | DocuSigned by: |
| **Name** | **Shanice Saunders** |
| **Title** | **Clinical Project Director** |
| **Date** | 8/23/2021 |

**Cornell University, for and on behalf of its Joan and Sanford I. Weill Medical College**

| | |
|---|---|
| **Signature** | DocuSigned by: Edward Walsh |
| **Name** | **Edward Walsh** |
| **Title** | **Senior Director, Financial Manager** |
| **Date** | 8/19/2021 |

**The New York and Presbyterian Hospital**

| | |
|---|---|
| **Signature** | DocuSigned by: Craig Albanese 3B2A809668AD4B6... |
| **Name** | **Craig Albanese, MD, MBA** |
| **Title** | **Group SVP, Chief Medical Officer, NYP** |
| **Date** | 8/21/2021 |

Uro Medical Clinical Trial Site Agreement Amendment

**Read and Acknowledged by**

| | |
|---|---|
| **Signature** | Bilal Chughtai, MD<br>9E3675C7210B49D... |
| **Name** | **Bilal Chughtai, MD** |
| **Title** | **Investigator** |
| **Date** | 8/19/2021 |




**AMENDMENT NO. 3 TO CLINICAL TRIAL SITE AGREEMENT**

This Amendment No. 3 ("Amendment No. 3") to the Clinical Trial Site Agreement is by and between Cornell University for and on behalf of its Joan and Sanford I. Weill Medical College ("WCMC") located at 1300 York Avenue, New York, NY 10065, and The New York and Presbyterian Hospital ("Hospital") a hospital affiliated with WCMC (together, WCMC and Hospital are the "Site"). Sponsor, WCMC, and Hospital are each a "Party" and together are the "Parties" in this Amendment No. 3, and Uro Medical Corporation ("Sponsor") a Corporation in accordance with Title 21 CFR Part 812.43, located at 1900 Glades Road Suite 500 Boca Raton, FL 33431. Sponsor, WCMC, and Hospitals are each a "Party") and together are the "Parties" in this Amendment No. 3.

WHEREAS, the Parties wish to amend certain sections of the Agreement;

THEREFORE, the Parties agree to the following changes within the Agreement:

This acts as a revision to Exhibit A "Compensation Form" of the original Agreement. The additional fees are amended to exclude Screen Failures. Therefore, screen failures are no longer an invoiceable fee.

***Signature page to follow***

Clinical Trial Site Amendment

IN WITNESS WHEREOF, the parties hereto have executed this Amendment No. 3 to the Agreement by proper persons duly authorized:

**FOR Uro Medical Corporation**

| | |
|---|---|
| **Signature** | DocuSigned by: Laura Tyler Perryman |
| **Name** | **Laura Perryman** |
| **Title** | **Chief Operating Officer** |
| **Date** | 8/23/2021 |

**FOR Uro Medical Corporation**

| | |
|---|---|
| **Signature** | DocuSigned by: |
| **Name** | **Shanice Saunders** |
| **Title** | **Clinical Project Director** |
| **Date** | 8/23/2021 |

**FOR Cornell University, for and on behalf of its Joan and Sanford I. Weill Medical College**

| | |
|---|---|
| **Signature** | DocuSigned by: Edward Walsh E0191E0AE07B458... |
| **Name** | **Edward Walsh** |
| **Title** | **Senior Director, Financial Management** |
| **Date** | 8/19/2021 |

**FOR The New York and Presbyterian Hospital**

| | |
|---|---|
| **Signature** | DocuSigned by: Craig Albanese |
| **Name** | **Craig Albanese, MD, MBA** |
| **Title** | **Group SVP, Chief Medical Officer, NYP** |
| **Date** | 8/19/2021 |

Clinical Trial Site Amendment

**Read and Acknowledged by**

| | |
|---|---|
| **Signature** | Bilal Chughtai, MD<br>9E3675C7210B49D... |
| **Name** | **Bilal Chughtai, MD** |
| **Title** | **Investigator** |
| **Date** | 8/19/2021 |